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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,698	07/03/2003	Bhiku G. Patel	03-40102-US	7194

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EXAMINER
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GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/613,698

Applicant(s)

PATEL ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment filed 09/28/2005.

Claim 20 has been canceled. Claims 1-19 are included in the prosecution.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-18, the expressions "substantially uniformly absorb", "substantially retained" and "substantially uniformly delivered" do not set forth the metes and bounds of the claim. Recourse to the specification does not define the expressions. Clarification is requested.

### ***Response to Arguments***

3. Applicant's arguments filed 09/28/2005 have been fully considered but they are not persuasive. Applicants argue that these expressions are definite and refer to several paragraphs of the present specification for definitions.

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With careful recourse to the referenced, applicants did not define the scope of any of the expressions “substantially” or “uniformly” in order to render the claims definite under the second paragraph requirement.

***Claim Rejections - 35 USC § 102***

4. Claims 1-3, 6, 7, 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,562,642 ('642).

US '642 discloses a non-woven pad impregnated by dermatologically active ingredients wherein the non-woven material is capable of absorbing a flowable liquid composition of the active ingredients (abstract; col.4, lines 37-39; col.5, lines 25-31; col.8, lines 21-34). The active ingredients include benzoyl peroxide, which is inherently insoluble, and antibiotic (col.10, lines 46-52). The composition is an emulsion and has low viscosity (col.12, lines 46-50; col.14, lines 38-40). The composition further comprises carbomer, and C<sub>12</sub>-C<sub>15</sub> alkyl benzoate (col.13, line 33; col.14, lines 60-65). The pad is contained in a container comprising aluminum foil layer in contact or sealed with thermoplastic layer that is sealable by heat, which packaging is not prone to premature rupture but provides ready dispensing of the package contents (col.3, lines 55-57; col.8, lines 45-59). The pad can be impregnated by antifungal agent or other dermatologically active agents (col.11, lines 50-52).

***Response to Arguments***

5. Applicant's arguments filed 09/28/2005 have been fully considered but they are not persuasive. Applicants argue that US '642 does not teach the claimed particle size or viscosity of the composition; thus, the reference does not anticipate the claims.

In response to this argument, applicants' attention is drawn to claims 1-3, 6, 7, 13-18 that are rejected as anticipated by US '642, these claims do not recite the particle

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size or the viscosity of the composition. Claims 4, 5, 8-12 that recite the particle size and the viscosity of the composition are not rejected under U.S.C. 102 over US '642.

***Claim Rejections - 35 USC § 103***

6. Claims 4, 5, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '642

The teachings of US '642 are discussed above. US '642 does not teach the claimed particle size and viscosity.

The claimed particle sizes and viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests the low viscosity of the liquid composition as implied by the flowability of the composition in order to be absorbed into the non-woven pad.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the non-woven pad impregnated with composition comprising benzoyl peroxide in a container as disclosed by the reference, and adjust the viscosity motivated by the desire of the reference to obtain flowability of the composition suitable for the composition to be absorbed into the pad, as also desired by applicants, with reasonable expectation of having pad that deliver active benzoyl peroxide when wiped to the skin.

***Response to Arguments***

7. Applicant's arguments filed 09/28/2005 have been fully considered but they are not persuasive. Applicants argue that US '642 does not teach the particle sizes or the viscosity such that the composition is substantially uniformly absorbed into the pad via capillary action and be substantially retained on the pad and not the container. The invention as a whole is not obvious because the reference does not teach each and every claim element.

In response to this argument, applicants' attention is drawn to the composition disclosed by US '642 that comprises the same elements disclosed by applicants that are retained in pad of non-woven material inside container made of metal and plastic, and it is expected for the same ingredients to have the same viscosity and form composition having the same net viscosity. It is also expected that the same composition to be absorbed into the pad made of the same material by the same mechanism, i.e. capillary action. It is further expected that the composition is absorbed into the pad and not into the container that is made of metal and plastic.

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). Therefore, US '642 does not need to teach every and each claim element under U.S.C. 103 (a). Regarding the particle sizes, they do not impart patentability to the claims since it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims are prima facie obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole taught by US '642.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,183,766 ('766) in view of US '642 and further in view of US 6,861,397 ('397) and US 5,821,237 ('237).

US '766 teaches non-woven pad impregnated by composition in the form of emulsion comprising: starch (col.7, line 33; col.10, line 46; col.16, lines 33-37); benzoyl peroxide (col.12, line 56); carbomer in amount of 0.01-10% (col.10, line 66; col.11, lines 8-35); water (col.18, example 1); glycerin (col.11, line 42); zinc lactate in amount of 0.1-10% (col.10, line 25); dimethicone in amount of 0.01-5% (col.4, line 41); and mixture of surfactants selected from glyceryl stearate and PEG 100 stearate, steareth 2, steareth 20, and polysorbate (col.14, lines 15-22).

US '766 does not teach the container. The reference also does not teach C<sub>12</sub>-C<sub>15</sub> alkyl benzoate which is well known in the cosmetic art.

US '642 teaches pad contained in a container comprising aluminum foil layer in contact or sealed with thermoplastic sealable by heat, which packaging is not prone to premature rupture but provides ready dispensing of the package contents (col.3, lines 55-57; col.8, lines 45-59). The pad is a non-woven pad impregnated with active



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ingredients include benzoyl peroxide, which is inherently insoluble, and antibiotic (col.10, lines 46-52). The composition has low viscosity (col.12, lines 46-50; col.14, lines 38-40). The composition further comprises carbomer, and C<sub>12</sub>-C<sub>15</sub> alkyl benzoate (col.13, line 33; col.14, lines 60-65).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pad impregnated with all the desired ingredients including C<sub>12</sub>-C<sub>15</sub> alkyl benzoate as disclosed by US '766 and to package the pad in the container disclosed by US '642, motivated by the teaching of US '766 that this packaging is not prone to premature rupture but provides ready dispensing of the package contents with reasonable expectation of having a non-woven pad impregnated with the desired effective liquid that is packaged in a container that is not prone to premature rupture but provides ready dispensing of the package contents.

US '766 in combination with US '642 do not teach sodium hydroxide, cetearyl alcohol, or EDTA, which are all known ingredients in the cosmetic art.

US '397 teaches topical composition that is highly effective in short time period and effectively deposits a topically active agent to provide residual benefit on the skin (abstract; col.5, lines 62-67). The composition comprises EDTA, sodium hydroxide and cetearyl alcohol (col.16, lines 36-45; col.61, appendix C).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide non-woven pad in a container wherein the pad is impregnated by the desired composition as disclosed by the combined teachings of US '766 and US '642 and add sodium hydroxide EDTA and cetearyl alcohol to the

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composition as taught by US '397, motivated by the teachings of US '397 that composition comprising those agent is highly effective in short time period and effectively deposits a topically active agent to provide residual benefit on the skin, with reasonable expectation of having pad in container that is highly effective in short time and deposits active agents when applied to the skin.

The combination of US '766, US '642 and US '397 does not teach the glycolic acid in the composition, which is known ingredient in the cosmetic art.

US '237 teaches topical composition impregnated into non-woven pad, the composition comprises EDTA to enhance the effect of the preservatives. The composition also comprises glycolic acid to improve the texture of the skin (col.16, lines 20-29; col.21, lines 60-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide non-woven pad in a container wherein the pad is impregnated by the desired composition as disclosed by the combined teachings of US '766, US '642 and US '397 and add glycolic acid and EDTA to the composition as taught by US '237, motivated by the teaching of US '237 that glycolic acid improves the texture of the skin and EDTA enhances the effect of preservatives, with reasonable expectation of having a pad in container that improves the skin texture when wiped to the skin, and well preserved at storage.

### ***Response to Arguments***

9. Applicant's arguments filed 09/28/2005 have been fully considered but they are not persuasive. Applicants argue that none of the cited references '766, '642, 397 teach

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the viscosity such that the composition is substantially uniformly absorbed into the pad via capillary action and be substantially retained on the pad and not the container. US '237 teaches high viscosity. The invention as a whole is not obvious because the reference does not teach each and every claim element.

In response to this argument, applicants' attention is drawn to the composition disclosed by the combined teachings of the references that will provide composition comprises the same elements disclosed by applicants that are retained in pad of non-woven material inside container made of metal and plastic, and it is expected for the same ingredients to have the same viscosity and form composition having the same net viscosity. It is also expected that the same composition to be absorbed into the pad made of the same material by the same mechanism, i.e. capillary action. It is further expected that the composition be absorbed into the pad and not into the container that is made of metal and plastic.

Regarding the argument that US '237 teaches high viscosity, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). US '237 is relied upon for the solely teaching that EDTA and glycolic acid are used for cosmetic composition impregnated into pad.

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated

by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims are prima facie obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole taught by the combined teaching of the references.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
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Art Unit 1615

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